EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel (BAP)
January 5, 2017

I. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG (FDA) AGENTS

A. PULMONARY IIs:

1. LAMA Agents: Tiotropium Soft Mist Inhaler (Spiriva Respimat)—UF Recommendation

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** tiotropium soft mist inhaler (Spiriva Respimat) be designated as formulary on the UF, based on clinical and cost effectiveness.

2. LAMA Agents: Tiotropium Soft Mist Inhaler (Spiriva Respimat)—Implementation Plan

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** the implementation become effective upon signing of the minutes.

Summary of Physician's Perspective:

- Since the May 2013 class review of the COPD drugs, there have been several new products that have entered the market. The various inhaler devices all have some advantages and disadvantages between them. For Spiriva Respimat, the new device is easier to use than the Spiriva Handihaler device, since there is no need to insert a capsule into the inhaler. However, the initial priming of the device may be difficult for some patients.

- In the DoD, the Handihaler product has 89% of the market share with over 54,000 unique users, compared to 9,500 users of the Respimat product. For the new Respimat formulation, over 88% of the usage is for patients with COPD, compared to 12% usage for patients with asthma.

- The Committee was reassured when the UPLIFT trial was reviewed that the original safety concerns with the Respimat device were not found in this prospective trial. Having Spiriva Respimat on the formulary provides another treatment option for patients with COPD.

Summary of Panel Questions and Comments:

There were no questions from the Panel. The Chair called for the vote on the UF Recommendation and Implementation Plan for the LAMA Agents : Triotropium Soft Mist Inhaler (Spiriva Respimate)

- **LAMA Agents: Triotropium Soft Mist Inhaler (Spiriva Respimate) —UF Recommendation**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: [signature]

☑ These comments were taken under consideration prior to my final decision

- **LAMA Agents: Triotropium Soft Mist Inhaler (Spiriva Respimate) —Implementation Plan**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: [signature]

☑ These comments were taken under consideration prior to my final decision

II. UNIFORM FORMULARY CLASS REVIEWS

A. ORAL ANTICOAGULANTS

1. Oral Anticoagulants—UF Recommendation

The P&T Committee recommended **(15 for, 0 opposed, 0 abstained, 0 absent)** the following:

- **UF:**
  - Warfarin (Coumadin; generic)
  - Apixaban (Eliquis)
  - Dabigatran (Pradaxa)
  - Rivaroxaban (Xarelto)
- **NF:** Edoxaban (Savaysa)

2. Oral Anticoagulants—Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation; and, 2) DHA send letters to beneficiaries who are affected by the UF decision.

Summary of Physician's Perspective:

- We have been reviewing the oral anticoagulants yearly since 2013. There were several reasons for reviewing the class again – there is an overall trend for declining warfarin use in DoD; the newer direct acting agents have now had enough time on the market to see if there are prescriber preferences for one newer product over another; the newer products have gained additional FDA indications; and to determine if the availability of a reversal agent would influence what newer products should be on the Formulary.

- We did talk with the Cardiology consultants – they recommended apixaban most often as being the preferred direct acting agent, however rivaroxaban was also mentioned due to the once daily dosing. Dabigatran is usually reserved for younger patients, due to bleeding risk. But dabigatran is the only product that has a reversal agent, and it was the first direct acting agent to gain FDA approval. Edoxaban was not endorsed by the cardiologists.

- Overall, the recommendation was unanimous for warfarin, apixaban, dabigatran and rivaroxaban to be on the Uniform Formulary. For edoxaban, non-formulary status was recommended; currently there are only 750 patients on it, compared to the over 200,000 patients on one of the other oral anticoagulants.

Summary of Panel Questions and Comments:

Dr. Anderson asked if there was a step-therapy program to require trial/failure of warfarin before using a newere anticoagulant.

Dr. Allerman replied that they did not recommend step therapy and the prescriber is free to use whatever is appropriate for the patient.

There were no more question or comments from the Panel. The Chair called for a vote on the UF Recommendation and Implementaion for the Oral Anticoagulants.

- **Oral Anticoagulants—UF Recommendation**

Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

Director, DHA: 

☐ These comments were taken under consideration prior to my final decision

- **Oral Anticoagulants—Implementation Plan**

Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

Director, DHA: 

☐ These comments were taken under consideration prior to my final decision

B. ANTILIPIDEMICS-1s (LIP-1s)

1. LIP-1s: PCSK9 Inhibitor Subclass—UF Recommendation

The P&T Committee recommended **(15 for, 0 opposed, 0 abstained, 0 absent)** the following, based on clinical and cost effectiveness:

- UF and step-preferred: evolocumab (Repatha)
- UF and non-step-preferred: alirocumab (Praluent)

Note that as part of this recommendation, all new users of alirocumab are required to try evolocumab first.

2. LIP-1s: PCSK9 Inhibitor Subclass—Manual Prior Authorization (PA) Criteria

Manual PA criteria for both PCSK9 inhibitors were recommended at the August 2015 P&T Committee meeting and implemented on October 30, 2015. The P&T Committee recommended **(15 for 0 opposed, 0 abstained, 0 absent)** maintaining the current manual PA criteria for alirocumab and evolocumab. The renewal PA criteria were updated to include prescriptions written by a primary care provider in consultation with a specialist who initially prescribed the agent. The step therapy requirement for a trial of evolocumab prior to use of alirocumab in new users is included in the manual PA criteria.

Full PA Criteria

a. PCSK9 Inhibitor: Alirocumab (Praluent)

Changes from November 2016 meeting are in BOLD.

All new users of alirocumab (Praluent) are required to try evolocumab (Repatha) first.

Manual PA Criteria—Alirocumab is approved if:

- A cardiologist, lipidologist, or endocrinologist initially prescribes the drug.
- The patient is at least 18 years of age.
- The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximally-tolerated doses.
- The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximally-tolerated doses, according to the criteria below:
  - The patient must have tried both atorvastatin (Lipitor) 40-80 mg and rosuvastatin (Crestor) 20-40 mg, OR
  - The patient must have tried any maximally-tolerated statin in combination with ezetimibe (Zetia), OR
  - If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate (Tricor), niacin, or bile acid sequestrants [Questran]), AND
  - The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy.
- For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below:
  - Intolerance
    - The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND
    - The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR
    - The patient has had a CREATINE kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. (These are signs of severe muscle breakdown leading to kidney damage, which a rare side effect of the statins.)

- Contraindication to statin
  - The contraindication must be defined.

- Praluent is not approved for any indication other than HeFH or clinical ASCVD.
- Praluent is not approved for patients who are pregnant or lactating.
- The dosage must be documented on the PA Form as either:
  - 75 mg every 2 weeks, or
  - 150 mg every 2 weeks.
- PA expires in one year.
- **PA criteria for renewal: After one year, PA must be resubmitted. The renewal request may be submitted by a primary care provider in consultation with the initial prescribing cardiologist, endocrinologist, or lipidologist. Continued use of Praluent will be approved for the following:**
  - The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND
  - The patient has documented adherence.

b. PCSK9 Inhibitor: Evolocumab (Repatha)

Changes from November 2016 meeting are in BOLD.

Manual PA criteria apply to all new users of evolocumab (Repatha).

Manual PA Criteria—Evolocumab is approved if:

- A cardiologist, lipidologist, or endocrinologist initially prescribes the drug.
- The patient is at least 18 years of age for HeFH and clinical ASCVD. For HoFH, patients as young as 13 years of age can receive the drug.
- The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol.
- The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses.

- The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximally-tolerated doses, according to the criteria below:
    - The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR
    - The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR
    - If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND
    - The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy.
- For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below:
    - Intolerance
        - The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND
        - The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR
        - The patient has had a creatine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use.
    - Contraindication to statin
        - The contraindication must be defined.
- Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD.
- Repatha is not approved for patients who are pregnant or lactating.
- The dosage must be documented on the PA Form as either:
    - 140 mg every 2 weeks, or
    - 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose.
- PA expires in one year.

- **PA criteria for renewal: After one year, PA must be resubmitted. The renewal request may be submitted by a primary care provider in consultation with the initial prescribing cardiologist, endocrinologist, OR lipidologist.** Continued use of Repatha will be approved for the following:
  - The patient has a documented positive response to therapy with
  - LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND
  - The patient has documented adherence.

3. LIP-1s: PCSK9 Inhibitor Subclass—UF and PA Implementation Plan

The P&T Committee recommended **(15 for, 0 opposed, 0 abstained, 0 absent)** an effective date of the first Wednesday after a 60-day implementation period.

Summary of Physician's Perspective:

- This is the first drug class review for these products, although PA criteria have been in place for over a year. Existing utilization is approximately 50-50 for Praluent vs. Repatha; and clinically the two products are very similar. Even though Repatha was previously made non formulary as an innovator drug, the equal market share does show that some providers are preferring Repatha over Praluent.

- When the cardiologists were surveyed, they expressed a slight preference for Repatha, which supports a switch from non-formulary to uniform formulary status. These provider preferences and market share support having Repatha back on the formulary, and making it step-preferred. The patients currently on Praluent will be able to remain on therapy, and it will still be on the formulary.

- We are just now coming up to the one year expiration date for the patients originally placed on these drugs. We will be reviewing how many patients submit the paperwork for the renewal PA. We also recognize that a cardiologist will start therapy, but will now allow a non-cardiologist to continue therapy, after consulting with the specialist.

- Once the outcomes studies are published, we will also look at the studies and decide if another class review is warranted.

Summary of Panel Questions and Comments:

Ms. Le Gette stated these drugs currently have a manual prior authorization criteria. Will it stay in place, or will it be an automated step therapy?

Dr. Allerman replied that it will be a manual prior authorization for Praluent. The requirement is to try Repatha first. The patients currently on Praluent will be grandfathered. It will not be an automated prior authorization.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Manual PA Criteria, and UF and PA Implementation Plan for LIP-1s : PCSK9 Inhibitoy Subclass.

- **LIP-1s: PCSK9 Inhibitor Subclass—UF Recommendation**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: [signature]

☐ These comments were taken under consideration prior to my final decision

- **LIP-1s: PCSK9 Inhibitor Subclass—Manual PA Criteria**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: [signature]

☑ These comments were taken under consideration prior to my final decision

- **LIP-1s : PCSK9 Inhibitor Subclass—UF and PA Implementation Plan**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: [signature]

☑ These comments were taken under consideration prior to my final decision

III. UF CLASS REVIEWS

A. INNOVATOR DRUGS

1. Innovator Drugs—UF Recommendation

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** the following:

- UF:
  - Antiemetics: aprepitant oral suspension (Emend)
  - Antihemophilic Factors: von Willebrand factor (Vonvendi)

- Ophthalmic Anti-Inflammatory Immunomodulatory Agents: lifitegrast ophthalmic solution (Xiidra)
- Topical Otic Antibiotic/Steroid Combinations: ciprofloxacin/fluocinolone acetonide otic solution (Otovel)

- NF:
  - Antigout Agents: lesinurad (Zurampic)
  - Antiplatelet Agents: aspirin/omeprazole (Yosprala)
  - Beta Blocker Combination Antihypertensive Agents: nebivolol/valsartan (Byvalson)
  - LAMA/Long-Acting Beta Agonists (LABA) combinations: glycopyrrolate/formoterol oral inhaler (Bevespi Aerosphere)
  - Miscellaneous Cardiovascular Agents: nitroglycerin sublingual (SL) powder (GoNitro)
  - Multiple Sclerosis Drugs: daclizumab (Zinbryta)
  - Opioid-Induced Constipation Drugs: methylnaltrexone tablets (Relistor)
  - Oral Contraceptives: norethindrone/ethinyl estradiol/iron (Taytulla)
  - Renin-Angiotensin Antihypertensive Agents (RAAs): lisinopril oral solution (Qbrelis)

2. Innovator Drugs—Manual PA Criteria

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** manual PA criteria for new users of Xiidra and Zinbryta, and for new and current users of Zurampic.

Full PA Criteria:

a. Innovator Drugs—Ophthalmic Anti-Inflammatory Immunomodulatory Agents: Lifitegrast Ophthalmic Solution (Xiidra)

Manual PA criteria apply to all new users of lifitegrast ophthalmic solution.

Manual PA Criteria

Coverage will be approved if:

1. Age ≥ 18 AND
2. Has documented diagnosis of moderate to severe inflammatory Dry Eye Disease AND
3. Drug is prescribed by an ophthalmologist or optometrist AND
4. Patient has failed to respond to an adequate trial of artificial tears.

Combination use of Xiidra and Restasis not allowed.

Off-label uses are NOT approved.

Prior Authorization does not expire.

b. Innovator Drugs—Multiple Sclerosis Drugs: Daclizumab (Zinbryta)

Manual PA criteria apply to all new users of daclizumab.

Manual PA Criteria

Coverage will be approved if:

1. Age ≥ 18 AND
2. Has documented diagnosis of relapsing multiple sclerosis AND
3. Has tried and had an inadequate response to two or more multiple sclerosis drugs.

Off-label uses are NOT approved.

Prior Authorization does not expire.

c. Innovator Drugs—Antigout Agents: Lesinurad (Zurampic)

Manual PA criteria apply to all new and current users of lesinurad.

Manual PA Criteria

Coverage will be approved if:

1. Age ≥ 18
2. The patient has chronic or tophaceous gout (where uric acid crystals form deposits around the joints)
3. The patient has a creatine clearance (CrCl) >45 mL/min (normal kidney function)
4. The gout patient has not achieved target serum uric acid level despite maximally-tolerated therapy with a xanthine oxidase inhibitor (drugs such as allopurinol).

Off-label uses are not approved.

Prior Authorization does not expire.

3. Innovator Drugs—UF and PA Implementation Plan

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** an effective date upon signing of the minutes in all points of service.

Summary of Physician's Perspective:

- For the innovator drugs recommended as non-formulary, clinically and cost effective alternative therapies are available on the formulary.
- Some of the new innovator drugs we have reviewed have prompted a full drug class review – as you saw with the PCSK9 inhibitors from this meeting. We will also re-review the Hepatitis C drugs at the February 2017 P&T Committee meeting, since there have been several new products approved in the past year.
- PA criteria were recommended for the dry eye drug (Xiidra), since there is already a PA for another drug in the class, Restasis. PAs criteria were recommended for the gout drug Zurampic, since we have existing step therapy for the xanthine oxidase inhibitor drugs allopurinol and Uloric. (Zurampic will not be part of the step). A PA was also recommended for the MS drug Zinbryta due to the specific indication and risk of adverse events.

- We will be looking at some metrics for the innovator program at the upcoming February 2017 meeting to see how many different drug classes have been reviewed, and how many products have been designated as non-formulary vs. formulary.

Summary of Panel Questions and Comments:

There were no questions from the Panel. The Chair called for the vote on the UF Recommendation, Manual PA Criteria, and UF and PA Implementation Plan for the Innovator Drugs.

- **Innovator Drugs—UF Recommendations**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

Director, DHA:

☑ These comments were taken under consideration prior to my final decision

- **Innovator Drugs—Manual PA Criteria**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

Director, DHA:

☑ These comments were taken under consideration prior to my final decision

- **Innovator Drugs—UF and PA Implementation**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

Director, DHA:

☑ These comments were taken under consideration prior to my final decision

IV. UTILIZATION MANAGEMENT

A. BASAL INSULINS

1. Basal Insulins: Insulin Degludec (Tresiba)—Manual PA Criteria

Tresiba is a new basal insulin indicated for glycemic, or blood sugar, control in adults with diabetes mellitus. Tresiba was reviewed in February 2016 as an innovator product and designated NF.

The P&T Committee recommended (**14 for, 0 opposed, 0 abstained, 1 absent**) manual PA criteria for Tresiba in new and current users. Despite its ultra-long duration of action and steady-state profile, Tresiba offers no clinically compelling advantages over existing basal insulins used to treat Type I or Type II diabetes (such as Lantus or Levimir). Patients will be required to try insulin glargine before using Tresiba.

Full PA Criteria:

Basal Insulins: Insulin Degludec (Tresiba)

Manual PA criteria apply to all new and current users of insulin degludec.

Manual PA Criteria

Tresiba is approved if:

a. Patient is age ≥ 18 AND

b. Patient has tried and failed or is intolerant to insulin glargine (Lantus).

Non-FDA approved uses are not approved.

Prior Authorization does not expire.

Basal Insulins: Insulin Degludec (Tresiba)—PA Implementation Period

The P&T Committee recommended (**14 for, 0 opposed, 0 abstained, 1 absent**) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

Summary of Physician's Perspective:

- The Committee did recommend "no grandfathering" here, so all patients will have to go through the PA process, which will affect about 3,000 patients. Lantus and Levemir are clinical alternatives that are both on the formulary. The Committee will be reviewing the basal insulins later in 2017.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel. The Chair called for the vote on the Manual PA Criteria and PA Implementation Plan for the Basil Insulins.

- **Basal Insulins: Insulin Degludec (Tresiba)—Manual PA Criteria**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: [signature]

☑ These comments were taken under consideration prior to my final decision

- **Basal Insulins : Insulin Degludec (Tresiba)—PA Implementation Plan**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: [signature]

☑ These comments were taken under consideration prior to my final decision

B. ANGALGESICS AND COMBINATIONS

1. Analgesics and Combinations: Butalbital/Acetaminophen (APAP) Tablets (Allzital)—Manual PA Criteria

Allzital is an oral tablet formulation containing butalbital and acetaminophen that is approved for tension or muscle headaches.

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** manual PA criteria for Allzital in new and current users, due to cost disadvantages compared to generic butalbital/APAP combinations.

Full PA Criteria:

Analgesics and Combinations: Butalbital/APAP Tablets (Allzital)

All new and current users of butalbital/APAP are required to undergo manual prior authorization.

Manual PA Criteria

Coverage will be approved if:

- Patient cannot tolerate generic oral tablet or capsule formulations of butalbital/APAP or butalbital/APAP/caffeine.

- Off-label uses are not approved.
- PA does not expire.

2. **Analgesics and Combinations: Butalbital/APAP Tablets (Allzital)—PA Implementation Plan**

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** an effective date of the first Wednesday after a 90-day implementation period in all points of service.

Summary of Physician's Perspective:

- This is the second bultalbital-containing product we have recommended a PA for. This product is another expensive formulation. Several cost effective generic formulations are available, and must be tried first, prior to Allzital.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel. The Chair called for the vote on the Manual PA Criteria and PA Implementation Plan for the Analgesics and Combination: Butalbital/APAP Tablets (ALZITAL).

- **Analgesics and Combinations: Butalbital/APAP Tablets (Allzital)—Manual PA Criteria**

Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: [signature]

☑ These comments were taken under consideration prior to my final decision

- **Analgesics and Combinations: Butalbital/APAP Tablets (Allzital)—PA Implementation Plan**

Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: [signature]

☑ These comments were taken under consideration prior to my final decision

C. TARGETED IMMUNOMODULATORY BIOLOGIC (TIBs) (DR. ALLERMAN)

1. TIBs: Adalimumab (Humira) and Ustekinumab (Stelara)—Manual PA Criteria

The TIBs were reviewed by the P&T Committee in August 2014 and automated PA (step therapy) and manual PA criteria were recommended for the class. Adalimumab (Humira) was selected as the UF step-preferred agent. In June 2016, adalimumab (Humira) received FDA approval for treatment of non-infectious intermediate, posterior and panuveitis in adult patients. (This is an inflammation of the pigmented areas of the eye which can lead to blindness). The PA criteria were updated for Humira to reflect its new FDA indication. Clinical data supporting several off-label uses for Humira were reviewed; these will be considered for coverage.\

Ustekinumab (Stelara) is UF and non-step-preferred; it is currently approved for rheumatoid arthritis and plaque psoriasis. In September 2016, Stelara received FDA approval for the treatment of adult patients with moderate to severely active Crohn's disease who have failed or were intolerant to treatment with immunomodulators, corticosteroids, or tumor necrosis factor (TNF) blockers. (Crohn's disease is a type of inflammatory bowel disease). The existing manual PA criteria were updated to include these new indications.

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** updating the manual PA criteria for Humira and Stelara to include their respective new indications.

Full PA Criteria

Targeted Immunomodulatory Biologics: Adalimumab (Humira)

Prior Authorization criteria was originally approved in August 2014 and implemented on February 18, 2015. **November 2016 changes to PA criteria are in BOLD.**

Manual PA criteria for non-infectious intermediate, posterior and panuveitis in adults apply to new patients.

- **Non-infectious intermediate, posterior and panuveitis in adults patients (November 2016)**

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis

- Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy, and when other systemic therapies are medically less appropriate

- Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade, or an inability to tolerate Remicade

- Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants

- Moderate to severe hidradenitis suppurativa (November 2015)

- **Non-infectious intermediate, posterior and panuveitis in adults patients (November 2016)**

Coverage approved for pediatric patients (age 4-17 years) with:

- Moderate to severe active polyarticular juvenile idiopathic arthritis

- Moderate to severely active Crohn's disease (≥ 6 years) who have had an inadequate response to corticosteroids, azathioprine, 6-mercaptopurine, or methotrexate.

Coverage for off-label uses not listed above. Please provide diagnosis and rationale for treatment. Supportive evidence will be considered.

PA does not expire.

Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan).

2. **Targeted Immunomodulatory Biologics: Ustekinumab (Stelara)**

November 2016 changes to PA criteria in bold.

Manual PA criteria for moderate to severe active Crohn's disease in adults apply to new patients.

Automated PA Criteria

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA Criteria

If automated criteria are not met, coverage is approved for Stelara if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF
- Adverse reactions to Humira not expected with requested non step-preferred TIB

AND

Coverage approved for patients ≥ 18 years with:

- Active psoriatic arthritis
- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- **Moderate to severe active Crohn's disease who have failed or intolerant to immunomodulators, corticosteroids, or TNF blockers. (November 2016)**

PA does not expire.

Non-FDA approved uses are not approved.

Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan).

3. TIBs: Adalimumab (Humira) and Ustekinumab (Stelara)—PA Implementation Plan

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** the implementation become effective upon signing of the minutes.

Summary of Physician's Perspective:

- Once again, we are updating the PAs for this drug class to be consistent with either new FDA approved indications or for off-label use where there is supporting literature. For Humira, there is supporting literature for ocular inflammatory disorders, including scleritis and Behcet'sdisease; pyoderma

gangrenosum, and sarcoidosis. If a provider sends in supporting literature for the TIBs, this can be considered for the PA.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel. The Chair called for the vote on the Manual PA Criteria and PA Implementation Plan for the TIBs: Adalimumab (Humira) and Ustekinumab (Stelara).

- **TIBs: Adalimumab (Humira) and Ustekinumab (Stelara)—Manual PA Criteria**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA:

☑ These comments were taken under consideration prior to my final decision

- **TIBs: Adalimumab (Humira) and Ustekinumab (Stelara)—PA Implementation Plan**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA:

☑ These comments were taken under consideration prior to my final decision

D. OPHTHALMIC ANTI-INFLAMMATORY/IMMUNOMODULATORY AGENTS: OPHTHALMIC IMMUNOMODULATORY AGENTS SUBCLASS

1. Ophthalmic Anti-Inflammatory/Immunomodulatory Agents: Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—Updated Manual PA Criteria

Restasis was reviewed in February 2016, with manual PA criteria recommended. Based on feedback from MTF providers and supporting literature, updates were made to the criteria to include treatment of atopic keratoconjunctivitis and vernal keratoconjunctivitis in pediatric patients (these are severe forms of allergies affecting the eyes, involving the corneas and eyelids) and in adults following LASIK surgery.

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** updating the Restasis manual PA criteria.

Full PA Criteria:

November 2016 updates are in BOLD.

Manual PA criteria apply to all new and current users of cyclosporine 0.05% ophthalmic emulsion.

PA criteria apply to all new users of Restasis.

- Current User is defined as a patient who has had Restasis dispensed during the previous 365 days at a Military Treatment Facility (MTF), a retail network pharmacy, or the Mail Order Pharmacy.
    - If there is a Restasis prescription in the past 365 days (automated lookback with Restasis as the qualifying drug), the claim goes through and no manual PA is required.
- New User is defined as a patient who has no had Restasis dispensed in the past 365 days.
    - If there is no Restasis prescription in the past 365 days, a manual PA is required.

Manual PA Criteria:

- Coverage is approved if one of the following is fulfilled:
    - Patient has diagnosis of keratoconjunctivitis sicca (KCS), **dry eye disease or dry eye syndrome** with lack of therapeutic response to at least 2 OTC artificial tears agents
    - Patient has ocular graft versus host disease
    - Patient has corneal transplant rejection
    - Patient has experienced documented corneal surface damage while using frequent artificial tears
    - **Restasis is prescribed by an ophthalmology/corneal specialist for a pediatric patient with a diagnosis of atopic keratoconjunctivitis (AKC) or vernal keratoconjunctivitis (VKC)**
    - **Patient has had LASIK surgery not more than 3 months previously. Note that therapy is limited to a maximum of 3 months of therapy after the procedure.**
- **The combination of Xiidra and Restasis is not allowed.**
- **For all indications, the patient must have had a trial of artificial tears.**

- Coverage is not approved for off-label uses such as, but not limited to:
    - Pterygia, which is growth of pink, fleshy tissue on the white part of the eye, and is common in people who spend a lot of time outdoors or have long periods of exposure to sunlight.
    - Blepharitis, which is chronic inflammation of the eyelids.
    - Ocular rosacea, where patients with rosacea develop eye symptoms, including a watery or bloodshot appearance, as well as irritation and burning or stinging of the eyes.
    - Contact lens intolerance

Prior Authorization expires in one year.

2. If there is a break in therapy, the patient will be subject to the PA again.

Ophthalmic Anti-Inflammatory/Immunomodulatory Agents: Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—PA Implementation Plan

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** the implementation become effective upon signing of the minutes.

Summary of Physician's Perspective:

The Restasis PA was updated based on some feedback from providers to expand the allowable off-label uses. Once again, there is supporting evidence for these conditions, or else there are no therapeutic alternatives, in the case of the pediatric population

Summary of Panel Questions and Comments:

Mr. Du Teil asked if there is a specific reason why it is limited to 3 months for use with LASIK surgery patients.

Dr. Allerman replied that was based on supporting literature. The LASIK is an off-label use; however, there are some data that suggests that it is appropriate for use at least 3 months afterwards. We didn't want to have that continued forever because the benefits decrease.

There were no more questions from the Panel. The Chair called for the vote on the Updated Manual PA Criteria and PA Implementation Plan for the Ophthalmic Anti-Inflammatory/Immunomodulatory Agents: Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)

- **OphthalmicAnti-Inflammatory/Immunomodulatory Agents: Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—Updated Manual PA Criteria**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

  For Director, DHA:

  ☑ These comments were taken under consideration prior to my final decision

- **OphthalmicAnti-Inflammatory/Immunomodulatory Agents: Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—PA Implementation Plan**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

  For Director, DHA:

  ☑ These comments were taken under consideration prior to my final decision

E. ORAL ONCOLOGY AGENTS

1. Oral Oncology Agents: Crizotinib (Xalkori)—Updated Manual PA Criteria

Xalkori is an oral oncologic agent used for the treatment of non-small cell lung cancer (NSCLC). Xalkori inhibits tyrosine kinases including anaplastic lymphoma kinase (ALK) and c-ros oncogene 1 (ROS). (This is a very specific target for the drug, which required a genetic test). Manual PA criteria have been in place since February 2012. The criteria were updated to add additional indications.

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** updating the manual PA criteria.

Full PA Criteria

Manual PA criteria apply to all new and current users of crizotinib.

Manual PA Criteria—Xalkori is approved if:

a. Patient has a documented diagnosis of ALK-positive NSCLC

OR

b. Patient has a documented diagnosis of ROS-1 positive NSCLC (November 2016)

PA does not expire.

Non-FDA approved uses are not approved.

2. Oral Oncology Agents: Crizotinib (Xalkori)—PA Implementation Plan

The P&T Committee recommended **(14 for, 0 opposed, 0 abstained, 1 absent)** the implementation become effective upon signing of the minutes.

Summary of Physician's Perspective:

This is another example of keeping up with expanded FDA approved indications for the oral oncology drugs.

Summary of Panel Questions and Comments:

There were no questions from the Panel. The Chair called for the vote on the Oral Oncology Agents: Crizotinib (Xalkori).

- **Oral Oncology Agents: Crizotinib (Xalkori)—Updated Manual PA Criteria**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: 

☑ These comments were taken under consideration prior to my final decision

- **Oral Oncology Agents: Crizotinib (Xalkori)—PA Implementation Plan**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA: 

☑ These comments were taken under consideration prior to my final decision

IV. FORMULARY STATUS UPDATE—NON-INSULIN DIABETES DRUGS (CAPT VONBERG)

A. Dipeptidyl Peptidase-4 (DPP-4) Inhibitors: Linagliptin/Metformin ER (Jentadueto XR)—Formulary Status Update

Linagliptin/metformin ER (Jentadueto XR) was reviewed as an innovator drug in August 2016 and designated NF and non-step preferred. Linagliptin/metformin IR (Jentadueto) is UF and non-step-preferred. Price parity now exists between Jentadueto and Jentadueto XR.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) designating Jentadueto XR as UF and non-step-preferred, with implementation upon signing of the minutes.

Summary of Physician's Perspective:

- Jentadueto XR has the same ingredients as Jentadueto, with the exception that the metformin component has extended release properties. This is an innovator drug where we have already reviewed the class, and since the cost effectiveness of Jentadueto XR was similar to the formulary product Jentadueto, the XR product was placed back on the formulary.

Summary of Panel Questions and Comments:

There were no questions from the Panel. The Chair called for the vote Formulary Status Update and the Implementation Plan for the Dipeptidyl Peptidase-4 (DPP-4) Inhibitors: Linagliptin/Metformin ER (Jentadueto XR)

- **Dipeptidyl Peptidase-4 (DPP-4) Inhibitors: Linagliptin/Metformin ER (Jentadueto XR)—Formulary Status Update**

Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

for Director, DHA:

☑ These comments were taken under consideration prior to my final decision

- **Dipeptidyl Peptidase-4 (DPP-4) Inhibitors: Linagliptin/Metformin ER (Jentadueto XR)—Implementation**

Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

for Director, DHA:

☑ These comments were taken under consideration prior to my final decision

V. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR 2008 (FY08) (CAPT VONBERG)

A. Section 703, NDAA FY08—Drugs Designated NF

The P&T Committee reviewed two drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were not in compliance with FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail

point of service and medical necessity at MTFs. These NF drugs will remain available in the mail order point of service without pre-authorization.

The P&T Committee recommended (**14 for, 0 opposed, 0 abstained, 1 absent**) the following products be designated NF on the UF:

- New Haven Pharma: aspirin ER (Durlaza) 162.5 mg oral capsules
- Tris Pharma: amphetamine (Dyanavel XR) 2.5mg/mL oral suspension

Note that both Durlaza and Dyanavel XR were previously recommended for NF placement as innovator drugs at the February 2016 P&T Committee meeting. The Director, DHA, approved the recommendation and implementation became effective in all points of service on May 5, 2016.

1. **Section 703, NDAA FY08—Pre-Authorization Criteria**

   The P&T Committee recommended (**14 for, 0 opposed, 0 abstained, 1 absent**) the following pre-authorization criteria for Durlaza and Dyanavel XR:

   a. Obtaining the product by home delivery would be detrimental to the patient; and,

   b. For branded products with products with AB-rated generic availability, use of the generic product would be detrimental to the patient.

   c. These pre-authorization criteria do not apply to any other point of service other than retail network pharmacies.

   Dyanavel XR is a Schedule II controlled substance, but is not typically used as first line therapy for attention deficit hyperactivity disorder, or used for acute therapy. If the home delivery requirement for Dyanavel XR impacts availability through the Mail Order Pharmacy, the P&T Committee will allow an exception to the Section 703 rule, and allow dispensing at the Retail Pharmacy Network.

2. **Section 703, NDAA FY08—Implementation Plan**

   The P&T Committee recommended (**14 for, 0 opposed, 0 abstained, 1 absent**) 1) an effective date of the first Wednesday after a 90-day implementation period for Durlaza and Dyanavel XR; and, 2) DHA send letters to beneficiaries affected by this decision.

   Summary of Physician's Perspective:

   For both products we recommended for NF status because there are cost-effective generic formulations or therapeutic alternatives available on the UF. The Pharmacy Operations Division does follow up with the affected manufacturers, to try to ensure compliance with the Section 703 requirements.

Summary of Panel Questions and Comments:

There were no questions from the Panel. The Chair called for the vote the Section 703, NDAA FY 08 Drugs Designated NF, Pre-Authorization Criteria, and Implementation Plan.

- **Section 703, NDAA FY08—Drugs Designated NF**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA:

☑ These comments were taken under consideration prior to my final decision

- **Section 703, NDAA FY08—Pre-Authorization Criteria**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA:

☑ These comments were taken under consideration prior to my final decision

- **Section 703, NDAA FY08—Implementation Plan**

  Concur : 10 Non-Concur : 0 Abstain : 0 Absent : 0

For Director, DHA:

☑ These comments were taken under consideration prior to my final decision

Brief Listing of Acronyms Used in this Summary

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms commonly used as acronyms in the Panel discussions are listed below for easy reference. The term "Panel" in this summary refers to the "Uniform Formulary Beneficiary Panel," the group who's meeting in the subject of this report.

- AB-Rated – Generic Drugs
- AKC – Atopic Kertoconjunctivitis
- ALK – Anaplastic Lymphoma Kinase
- APAP – Butalbital/Acetaminophen
- ASCVD – Atherosclerotic Cardiovascular Disease
- BAP – Beneficiary Advisory Panel
- BCF – Basic Core Formula
- BIA – Budget Impact Analysis
- CEA – Cost-Effectiveness Analysis
- CFR – Code of Federal Regulations
- CHF – Congestive Heart Failure
- CK – Creatine Kinase
- CMA – Cost Minimization Analysis
- COPD – Chronic Obstructive Pulmonary Disease
- CrCL – Creatine Clearance
- CV – Cardiovascular
- DFO – Designated Federal Office
- DHA – Defense Health Agency
- dL – Deciliter
- DOAC – Direct Oral Anticoagulant
- DoD – Department of Defense
- DPP-4 – Non-Insulin Diabetes Drugs
- FACA – Federal Advisory Committee Act
- FDA – Food & Drug Administration
- FEV1 – Forced Expiratory Volume in One Second
- GI – Gastrointestinal
- HeFH - Heterozygous Familial Hypercholesterolemia
- HoFH - Homozygous Familial Hypercholesterolemia
- KCS - Keratoconjunctivitis Sicca
- LABA - Long Acting Beta Agonists
- LAMA – Long-Acting Muscarinic Antagonist
- LASIK - Laser-Assisted in Situ Keratomileusis
- LDL – Low-Density Lipoprotein

- LIP-1S - Antilipidemics-1
- MHS – Military Health Service
- mL – Milliliter
- MTF – Military Treatment Facility
- NDAA – National Defense Authorization Act
- NF – Non-Formulary
- NSCLC – Non-Small Cell Lung Cancer
- NVAF – Non-Valvular Atrial Fibrillation
- P&T – Pharmacy & Therapeutics
- PA – Prior Authorization
- PCSK9 - Proprotein Convertase Subtilisin/Kexin Type 9
- ROS - Receptor Tyrosine Kinase
- TIBs – Targeted Immunomodulatory Biologic
- TIOSPIR – trial demonstrates comparable long-term safety of tiotropium delivered via Respimat and HandiHaler in COPD patients
- TNF – Tumor Necrosis Factor
- UF – Uniform Formulary
- ULN – Upper Limit of Normal
- UPLIFT – Use Portable Lifts in Facilitating Transfers
- VKC – Vernal Keratoconjunctivitis
- VTE – Venous Thromboembolism
- XR – Extended Release